UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE BRISTOL-MYERS SQUIBB CO. CVR SECURITIES LITIGATION	:	Case No. 1:21-cv-08255 (JMF) ORAL ARGUMENT REQUESTED

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED COMPLAINT

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PRELIMINARY STATEMENT

Plaintiffs now admit the statements challenged in their second amended complaint were "technically true." Opp. at 21 [ECF No. 121]. In their view, those "true" statements gave rise to claims for securities fraud because the defendants did not disclose an alleged "secret plan to deliberately miss the CVR deadline" so that BMS could avoid payment on the CVRs. *Id.* at 22. This Court previously recognized plaintiffs had not pleaded facts to support that theory, *see In re Bristol-Myers Squibb Co. CVR Sec. Litig.*, ___ F. Supp. 3d ____, 2023 WL 2308151, at *5-7 (S.D.N.Y. Mar. 1, 2023), and the opposition only confirms plaintiffs' failure to address that gap in their allegations.

In the second amended complaint, plaintiffs added a few more hindsight opinions from an anonymous "expert," allegations from a few more confidential witnesses, and a description of the responsibilities of two internal BMS committees. *None* of those new allegations identifies an undisclosed contrary fact known by the defendants at the time of any challenged statement. An expert's after-the-fact opinion that liso-cel *should have been* approved earlier than it was does not support a plausible inference of either falsity or scienter, much less a "strong" one. 15 U.S.C. §§ 78u-4(b)(1), (b)(2). Confidential witness allegations about the types of information Dr. Caforio or Dr. Hirawat "would have been aware of," Compl. ¶ 177, and descriptions of the responsibilities of BMS internal committees, fall similarly short.

Rather than fraud, the new allegations, like the old ones, depict the defendants providing accurate updates about an inherently uncertain FDA approval process that unfolded in the midst of "an unprecedented pandemic." *BMS CVR Sec. Litig.*, 2023 WL 2308151, at *6. That plaintiffs might be disappointed there were "setbacks" in that process does not give them a basis to sue for fraud. Plaintiffs have had several chances to plead a viable claim of securities fraud, and they still have not done so. The second amended complaint should be dismissed with prejudice.

ARGUMENT

I. PLAINTIFFS' REMAINING CLAIMS SHOULD BE DISMISSED.

A. Plaintiffs Still Do Not Allege an Actionable Misstatement.

1. None of the Challenged Statements Was False or Misleading.

Falsity is the first element of any claim for securities fraud, but plaintiffs do not attempt to address that threshold issue until the closing pages of their opposition. There, they acknowledge that all of the statements they challenge as fraudulent were, in fact, "technically true." Opp. at 21. Plaintiffs' argument that the defendants failed to disclose a "secret plan" to avoid timely FDA approval of liso-cel does not satisfy the PSLRA requirement to identify each allegedly false statement and "the reason or reasons" it was misleading, 15 U.S.C.§ 78u-4(b)(1), based on information available "at the time it was made." *BMS CVR Sec. Litig.*, 2023 WL 2308151, at *3.

Elaborating on their factually unfounded central theory, plaintiffs argue that all of the challenged statements were false, even though "technically true," because they failed to disclose the defendants' alleged "knowledge of the FDA submission and inspection failures that would likely result in the Company's not meeting the CVR deadline." Opp. at 21. But plaintiffs have not pleaded falsity under that theory either.

Plaintiffs argue that a BMS press release announcing the completion of the liso-cel application on December 18, 2019, was misleading because it "did not disclose that [BMS] had waited an *unnecessary* twenty-nine days to do so, or its knowledge that the submission was wholly inadequate." *Id.* at 21 n.23 (emphasis added); *see* Compl. ¶ 237. But plaintiffs have not pleaded facts to show that the alleged filing delay was "unnecessary" or that BMS knew "the submission was wholly inadequate." Indeed, the complaint alleges the FDA *accepted* the liso-cel application and granted it "Priority Review." Compl. ¶ 134. Similarly, plaintiffs contend a later disclosure – that the FDA had deemed a BMS response to an agency request for more information about the

liso-cel application to be a "major amendment" – was misleading because the statement did not disclose that the FDA's decision "easily could have [been] avoided[.]" Opp. at 21 n.23; *see* Compl. ¶ 242. BMS had no duty under the federal securities laws to engage in such self-flagellation, *see, e.g.*, *In re Citigroup, Inc. Sec. Litig.*, 330 F. Supp. 2d 367, 377 (S.D.N.Y. 2004), but the complaint offers no contemporaneous facts to support that hindsight critique in any event.[1]

Rather than offering the necessary allegations of contemporaneous fact, plaintiffs rely on hindsight opinions from an unidentified "FDA Biologics Expert" to claim these statements were false. But "opinions cannot substitute for facts under the PSLRA." *Ark. Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343, 354 (2d Cir. 2022). None of the opinions offered by plaintiffs' unidentified expert – including their "statistical analysis" of the timelines for FDA applications of other product candidates – plausibly suggest that any challenged statement was misleading based on "information available at the time" to BMS or the other defendants. *Scott v. Gen. Motors Co.*, 46 F. Supp. 3d 387, 394 (S.D.N.Y. 2014), *aff'd*, 605 F. App'x 52 (2d Cir. 2015).[2]

Nor can plaintiffs establish falsity through their latest theory that the challenged statements allegedly "failed to disclose [BMS's] utter recklessness, at best, with respect to getting Liso-cel

[1] Plaintiffs make essentially the same falsity argument for their "four newly alleged misstatements – Statements 2, 15, 16, and 17." Opp. at 21 n.24; *see* Compl. ¶¶ 235, 263, 265, 267. The complaint fails to plausibly allege the falsity of those statements for the same reasons.

[2] Plaintiffs mistakenly rely on *In re Ambac Fin. Grp., Inc. Sec. Litig.*, 693 F. Supp. 2d 241 (S.D.N.Y. 2010), where Judge Buchwald declined to certify for interlocutory appeal a question concerning the weight to be given "to statements by confidential witnesses or conclusions of confidential experts," because resolution of that issue would not materially advance the ultimate termination of the litigation. *Id.* at 283. Unlike here, the *Ambac* plaintiffs pleaded facts from contrary internal reports. *Id.* at 284. In addition, the unnamed experts offered valuation opinions for financial instruments Ambac had insured to show that Ambac's portfolio was deteriorating in line with relevant market indices, a contemporaneous fact that conflicted with challenged statements. *Id.* at 283. The opinions of the "FDA Biologics Expert" here do not raise any similar conflict but instead amount to no more than hindsight second-guessing.

approved on time." Opp. at 22. As with plaintiffs' allegations of an undisclosed "secret plan," that assertion is not grounded in any fact available at the time. Defendants were not required to "be clairvoyant; they [were] only responsible for revealing those material facts reasonably available to them." *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 543 (S.D.N.Y. 2015) (quoting *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000)).

2. The PSLRA Safe Harbor Bars Liability for Many Statements.

Plaintiffs cannot evade application of the statutory safe harbor for forward-looking statements through their factually unmoored assertion that the defendants never intended to permit the CVR milestones to be satisfied. Opp. at 23. The safe harbor obviously applies to the forward-looking statements defendants previously identified, all of which "address[ed] what defendants expect[ed] to occur in the future[]" in the FDA approval process. *BMS CVR Sec. Litig.*, 2023 WL 23018151, at *8; *In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 758 (S.D.N.Y. 2018); *see* Defs. Mem. at 16 (Statements 1, 2, 5, 6, 8-12, 14, 16, 18-20).

Plaintiffs are further mistaken in contending that these statements "relate[]d to then-existing facts and conditions." Opp. at 23. The only "then-existing fact" plaintiffs identify for this argument is plaintiffs' own unfounded assertion that BMS allegedly had no intention of allowing the CVR milestones to be met. As the Court already recognized, plaintiffs are confusing "the question of whether a statement is forward-looking with the applicability of the safe harbor's 'actual knowledge' prong[,]" which would "rip a large hole in [the PSLRA], and result in an exception swallowing the rule." *BMS CVR Sec Litig.*, 2023 WL 2308151, at *8 (citation omitted).[3]

[3] Plaintiffs' only argument for "actual knowledge" is their conclusory assertion that the defendants "knew the CVR deadline would be missed." Opp. at 23 n.27. Plaintiffs have not identified any "specific, *contemporaneous* reports or statements showing" that any defendant knew that it was preordained that at least one of the CVR milestones would be missed. *In re Nielsen Holdings PLC Sec. Litig.*, 510 F. Supp. 3d 217, 231 (S.D.N.Y. 2021) (emphasis added).

Plaintiffs' arguments that the cautionary language was not meaningful are equally unpersuasive. Opp. at 23-24. As this Court has recognized, BMS warnings that investors "may not receive any payment on the CVRs" and that "the CVRs may ultimately have no value" were not "boilerplate." *BMS CVR Sec. Litig.*, 2023 WL 23018151, at *9. The risk factor disclosures were "'extensive and specific,' substantive, and tailored to the risks involved." *Id.* Plaintiffs' separate contention that cautionary language was not meaningful because it did not disclose an alleged plan to delay FDA approval "once again conflate[s] distinct provisions of the PSLRA's safe harbor – this time, the actual knowledge and meaningful cautionary language prongs of the statute." *Id.*

3. Expressions of Corporate Optimism Are Not Actionable.

Plaintiffs similarly fail to explain how statements concerning the status of the FDA approval process or BMS's intention to work with the FDA were materially false or misleading. Opp. at 22; *see* Defs. Mem. at 17 (Statements 5, 7, 11-12, 14, 16, 19, 20). Such "indefinite statements of corporate optimism" are not actionable unless "the speaker knew that the contrary was true." *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 173-74 (2d Cir. 2020); *see also Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 189 (2015). Plaintiffs have not plausibly alleged such knowledge here.

B. Plaintiffs Have Not Alleged Facts Supporting a "Strong Inference" of Scienter.

In its dismissal opinion, the Court concluded that plaintiffs had not alleged facts giving rise to an inference of scienter that was "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *BMS CVR Sec. Litig.*, 2023 WL 2308151, at *3. The second amended complaint does not cure that pleading failure. Just as before, "[t]he more compelling inference to be drawn from the pleaded facts is that both BMS and the FDA experienced embarrassing, but not 'extreme' setbacks during an unprecedented pandemic." *Id.* at *6.

1. Plaintiffs Have Not Addressed the Identified Problems with Their Motive Allegations.

The second amended complaint relies on substantially the same motive allegations that already were rejected by the Court as inadequate in plaintiffs' previous complaint. Defs. Mem. at 18-20. Plaintiffs do not claim otherwise in their opposition. Opp. at 15. Their reframed arguments about the alleged importance of the Celgene merger to BMS, and purported criticisms of BMS leadership based on alleged underperformance in the company's stock price, do not support an inference that Dr. Caforio or Dr. Hirawat stood to "benefit[] in some concrete and personal way from" securities fraud. *BMS CVR Sec. Litig.*, 2023 WL 2308151, at *4. Plaintiffs' arguments suggest, at most, "the normal profit-making incentives of any corporate officer" and do not support any inference of fraudulent intent. *Gluck v. Hecla Mining Co.*, ___ F. Supp. 3d ____, 2023 WL 2161958, at *9 (S.D.N.Y. Feb. 22, 2023).[4]

2. Plaintiffs Have Not Alleged Conscious Misbehavior or Recklessness.

As with their other arguments, plaintiffs' opposition bases their arguments about the defendants' alleged conscious misbehavior or recklessness on the hindsight opinions of their "FDA Biologics Expert," with minor additions from confidential witnesses about events preceding the FDA's approval of liso-cel. Opp. at 7-13.

To plead "strong circumstantial evidence" of scienter, a complaint must allege "conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that

[4] Plaintiffs miss the mark in their attempt to sidestep the economic illogic of their central allegation that the defendants intentionally stalled the FDA approval process to avoid payment of $6.4 billion to holders of the CVRs. Opp. at 15 n.14. Plaintiffs' motive theory "defies economic reason" because any such intentional delay would have resulted in a lawsuit seeking equivalent damages for breach of the governing CVR Agreement. *See ECA, Loc. 134 IBEW Jt. Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 203 (2d Cir. 2009).

the defendant must have been aware of it." *Gissin v. Endres*, 739 F. Supp. 2d 488, 503 (S.D.N.Y. 2010). That requires allegations of: "(1) *specific* contradictory information [that] was available to the defendants (2) *at the same time* they made their misleading statements." *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 588 (S.D.N.Y. 2011) (emphasis in original). Where, as here, "there is no evidence of motive, [] the strength of the circumstantial allegations must be correspondingly greater." *BMS CVR Sec. Litig.*, 2023 WL 2308151, at *5.[5]

As already discussed, plaintiffs have not alleged any contradictory fact that was available to the defendants at the time of the challenged statements, much less information that might support plaintiffs' fraud theory. Opp. at 7-13. The opposition glosses over this pleading failure by collapsing the timeline of events that unfolded over the course of more than a year. *See id.* at 7. When the challenged disclosures are considered in context, based on events as they actually occurred, it becomes even clearer that plaintiffs have alleged "mismanagement," at best, which is not actionable under Rule 10b-5. *BMS CVR Sec. Litig.*, 2023 WL 2308151, at *6; *see Santa Fe Indus., Inc. v. Green*, 430 U.S. 462, 479 (1977) ("'Congress by § 10(b) did not seek to regulate transactions which constitute no more than internal corporate mismanagement.'"); *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 562 (S.D.N.Y. 2014) ("This narrative requires the Court to stretch allegations of, at most, corporate mismanagement into actionable federal securities fraud. This is not the law.").

After-the-fact opinions of plaintiffs' unnamed "FDA Biologics Expert" add nothing to the scienter analysis. As the Court correctly observed in its dismissal decision, "it is well established

[5] Plaintiffs express doubt that this is the rule. Opp. at 6-7 n.5. The Second Circuit disagrees. *See, e.g.*, *Bristol-Myers Squibb Co.*, 28 F.4th at 355 ("If no motive or opportunity . . . is shown, the circumstantial evidence of conscious misbehavior 'must be correspondingly greater[.]'").

that an expert may not opine on the state of mind or knowledge of a party." *BMS CVR Sec. Litig.*, 2023 WL 2308151, at *6. Plaintiffs avoid discussion of that point, choosing to focus instead on the motion to dismiss standard. Opp. at 5 & n.3. But irrespective of whether courts have allowed allegations in other contexts based on alleged expert opinions, the hindsight views offered here do not support an inference of scienter because they do not suggest that any challenged statement was in conflict with internal information known by the defendants at the time. *See supra* at 3 n.2.

Speculation attributed to alleged former BMS employees, CW #9 and CW #10, also does not support any inference of fraudulent intent. The opposition is at odds with plaintiffs' actual allegations concerning CW #9, who allegedly offered plaintiffs nothing beyond a description of the types of reports that were provided to Dr. Caforio and Dr. Hirawat and did not allege that either officer knew information that contradicted the statements challenged as fraudulent. Opp. at 10; *see* Compl. ¶ 177. Plaintiffs admit that allegations attributed to CW #10 amount to no more than speculation about the types of information Dr. Caforio "should have" received about the liso-cel approval process. Opp. at 10; *see* Compl. ¶ 172 n.11 ("As CW #10 observed during [p]laintiffs' investigation, individuals like [d]efendant CEO Caforio would have had a "fiduciary duty to his shareholders to know about" the FDA approval process for liso-cel . . ."). The addition of these confidential witnesses does nothing to cure the pleading failure the Court identified in its dismissal decision. *BMS CVR Sec. Litig.*, 2023 WL 2308151, at *5 ("[T]he relevant question is whether the allegations . . . support an inference that the Executive Defendants *knew* (or should have known) of the alleged missteps. They do not.").

Plaintiffs' allegations about the responsibilities of two internal committees at BMS also add nothing. Opp. at 8-9. Providing a description of those committees' roles, while failing to add any factual allegation that conflicts with the challenged statements, does not support an inference

that the defendants were acting with an intention to defraud. *Africa v. Jianpu Tech. Inc.*, 2022 WL 4537973, at *11 (S.D.N.Y. Sept. 28, 2022) ("general allegations about the responsibilities of [the committees], and what [their] members might have learned" are "speculative and, thus, insufficient to show scienter") (Furman, J.); *In re Satyam Computer Servs. Ltd. Sec. Litig.*, 915 F. Supp. 2d 450, 479 (S.D.N.Y. 2013) (plaintiffs failed "to identify . . . what information [] the [audit committee] defendants had a duty to monitor and . . . failed to monitor, [that] would have led them to discover the fraud").[6]

Finally, because plaintiffs' latest scienter allegations do not materially change allegations that the Court previously found insufficient, the second amended complaint also necessarily fails to plead "corporate scienter." *BMS CVR Sec. Litig.*, 2023 WL 23018151, at *7. Plaintiffs have not alleged facts sufficient to support the requisite "strong inference" of scienter as to any person "whose intent could be imputed to" BMS, nor have plaintiffs alleged that the alleged misstatements "would have been approved by corporate officials sufficiently knowledgeable about [BMS] to know that [they] were misleading." *Id.*

C. The "Controlling Person" Claim Should Be Dismissed.

Plaintiffs' failure to allege a primary violation also requires dismissal of the "controlling person" claim under Exchange Act § 20(a). *JP Morgan Chase Co.*, 553 F.3d at 206-07.[7]

[6] The "core operations" doctrine also does not support an inference of scienter. Even if that doctrine "remains valid in light of the PSLRA," plaintiffs have not alleged "that the operation in question constitute[s] nearly all of [BMS's] business . . . ." *BMS CVR Sec. Litig.*, 2023 WL 2308151, at *6. Plaintiffs use the missed CVR payment as a stand-in for this purpose. Opp. at 13 n.11. But the question is whether the CVR-related applications constituted nearly all of BMS's business – not whether the missed CVR payment allegedly "increased [BMS's] net earnings." *Id.*

[7] Plaintiffs also fail to plead loss causation, as they do not tie any CVR price decline following updates on the FDA approval process "to a corrective disclosure regarding the falsity" of any prior statement. *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 175 (2d Cir. 2005). There was no "concealed risk," Opp. at 24 – only accurate disclosures that resulted in "concomitant market dissatisfaction[.]" *Born v. Quad/Graphics, Inc.*, 521 F. Supp. 3d 469, 494 (S.D.N.Y. 2021).

II. DISMISSAL SHOULD BE WITH PREJUDICE.

Plaintiffs' request for still another opportunity to amend their complaint – based on unspecified "outstanding FOIA requests," Opp. at 25 n.30 – should be denied. That request was not made in the form of a motion, as required. *See, e.g.*, *In re Citigroup S'holder Deriv. Litig.*, 2009 WL 2610746, at *13 (S.D.N.Y. Aug. 25, 2009) (rejecting as procedurally improper plaintiffs' request for leave to amend made in opposition brief). Moreover, plaintiffs already have had two opportunities to amend their complaint without success. Because "plaintiffs have identified no additional facts or legal theories . . . they might assert if given leave to amend[,]" they should not be granted a third opportunity. *City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 188 (2d Cir. 2014); *see, e.g.*, *Born*, 521 F. Supp. 3d at 495 (dismissing complaint with prejudice).

CONCLUSION

For the foregoing reasons and those stated in defendants' opening memorandum, the second amended complaint should be dismissed in its entirety and with prejudice.

Dated: New York, New York
June 23, 2023

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